10-1-2017

The Ongoing Quest for the Holy Bone Graft Grail: Scientific Progress, Economic Bonanza, or Quixotic Quagmire?

Jens R Chapman
Swedish Neuroscience Institute

Karsten Wiechert

Jeffrey C Wang

AOSPINE

Global Spine Journal
2017, Vol. 7(7) 602

DOI: 10.1177/2192568217733470
journals.sagepub.com/home/gsj
SAGE

The Ongoing Quest for the Holy Bone Graft Grail: Scientific Progress, Economic Bonanza, or Quixotic Quagmire?

The market for bone grafts continues to be ever-expanding in products, device categories, and volumes applied. Market analysts consistently see bone graft substitutes as an investment opportunity, quoting our increasingly aging and sicker population and apparent disenchantment with the gold standard—mainly iliac crest graft—as the leading driver for this ongoing development. Spine surgery, and spine surgeons, are a major contributor of bone graft substitute use—and there is no end in sight as spine surgery continues to increase.

Numbers are staggering, especially as there was literally no "market" for bone graft substitutes until the 1990's. Recent market analyses place the US market for bone graft substitutes at 2.3 to 3.5 billion USD by 2017 with an increase of a billion dollars through 2025 based on an annual composite growth rate of over 5 %. For spine surgeons, the market array has become an increasingly bewildering experience filled with promises and scientific detail. The golden triangle of osteogenesis, —induction and—conduction theoretically achievable with autograft has so far eluded a satisfactory replication with allografts (structural, machined, demineralized, or cell enhanced), synthetic (glasses, ceramics, collagen, hyaluronic acid, and BMP) and blended devices (assembled from allografts and synthetic devices). The market for autograft processing and augmentation techniques (ie, bone marrow aspirates, platelet and stem cell enrichment technologies) remains intact without seemingly abating the appeal of allograft and synthetic bone graft substitutes.

A fair number of articles in spine publications (*Global Spine Journal* included) and elsewhere are dedicated to demonstrating the healing propensities of various graft materials with few, if any, accepted standards to measure actual healing outcomes. We still lack an ideal animal model—the transferability of data to humans and their respective clinical scenarios is still doubtful, and we remain unsure what radiographic and clinical outcomes data best apply for bone graft related research.

Level 1 data is available for a number of products (2 BMP's, a peptide based synthetic, a bioactive glass and a demineralized bone matrix), all leading to favorable findings in support of the respective devices, but the ensuing lengthy and narrow approvals process and lingering questions about efficiency of the product lines make the likelihood that others will want to pursue this level of research with all its sequelae increasingly doubtful. As the variety of products and their associated performance claims have risen, so have their prices—making affordability of many of these products a real issue as hospital administrators and third party payors have started to intervene directly.

The health care value equation in spine surgery applies almost nowhere more than in the selection and application of bone graft materials and their substitutes. The implications of autograft in terms of its contribution to patient outcomes and complications, its donor site morbidity, and limited supply or viability frequently receive insufficient attention of advocated of its use.

All things considered, we are nowhere close to a resolution of the bone graft question. The ongoing multiplication of products and technologies will likely continue to confuse clinical results reporting, and real macrodata based on reoperation rates of fusion patients over 2, 5, and 10 years in the area of previous surgery using generally accepted radiographic and clinical findings will remain elusive. Perhaps a stratified risk-based approach using patient variables and combining that with available biological data may offer a more immediate help in combining the best osteobiologics technology with a specific patient' needs.

Jens R. Chapman, MD
Swedish Neuroscience Institute,
Swedish Medical Center,
Seattle, WA, USA
Karsten Wiechert, MD
Schön-Klinik München Harlaching Academic Hospital,
Paracelsus Medical University Salzburg
Munich, Germany
Jeffrey C. Wang, MD
USC Spine Center, Los Angeles, CA, USA